ActiFlo Indwelling Bowel Catheter System

Product Information

**NON STERILE:** The ActiFlo Indwelling Bowel Catheter System is constructed primarily of silicone materials. All system components are sterile. Single patient use only.

**CONTRAINDICATIONS**

- Do not use if the patient’s distal rectum cannot accommodate the inflated volume of the retention cuff, or if the distal rectal canal is severely stenotic (e.g., secondary to tumor, inflammatory condition, radiative injury, scarring).
- Do not use if package has been opened or damaged.
- Do not use on patients having impacted stool.
- Do not use on patients with compromised mental or cognitive function (e.g., dementia).
- Do not use on patients with severe tenesmus, or patients who experienced tenesmus or severe pain after insertion of the catheter.
- Do not use if the patient has known sensitivities or allergies to the materials used in this device.

**WARNINGS**

- Feces contain infectious material. Protect from splatter which may occur when disconnecting or emptying the irrigation bags.
- Use only gravity or slow manual irrigation. Do not connect mechanical pumping devices to catheter irrigation lumen.
- Do not connect irrigation bag to external venting.

**ADVERSE EVENTS**

- Feces contains infectious material. Protect from splatter which may occur when disconnecting or emptying the irrigation bags.

**CAUTIONS**

- Patients with severe tenesmus, or patients who experience tenesmus or severe pain after insertion of the device, may not tolerate the catheter in place.
- Avoid inserting anything (e.g., thermometers, suppositories, etc.) into the anal canal or catheter in place to prevent patient injury or catheter damage.
- Patients whose skin may be harmed by stool should not use this device.

**PATIENT INSTRUCTIONS**

- Use only gravity or slow manual irrigation. Do not use mechanical or manual pumping devices to catheter irrigation lumen.
- Do not overinflate retention cuff or stop-flow balloon.
- Do not puncture the catheter body. Always use the catheter irrigation lumen. Do not puncture the catheter body with sharp objects.
- Do not contact the catheter with any sharp or smooth objects.
- Do not use on patients with compromised mental or cognitive function (e.g., dementia).

**INSTRUCTIONS FOR USE**

- Use only gravity or slow manual irrigation. Do not connect mechanical pumping devices to catheter irrigation lumen.
- Do not puncture the catheter body. Always use the catheter irrigation lumen. Do not puncture the catheter body with sharp objects.
- Do not contact the catheter with any sharp or smooth objects.
- Do not use on patients with compromised mental or cognitive function (e.g., dementia).

**DISTRIBUTED BY**

Distributed by Hollister Incorporated
Libertyville, IL USA
1.888.740.8999

©2011 Hollister Incorporated. Printed in USA
011350-271

InstaFlo Bowel Catheter System

Product Information

**NON STERILE:** The InstaFlo Bowel Catheter System is constructed primarily of silicone materials. All system components are sterile. Single patient use only.

**CONTRAINDICATIONS**

- Do not use in patients who may have had their distal rectum significantly altered by surgical resection or reconstruction.
- Do not use if the patient’s distal rectum cannot accommodate the inflated volume of the retention cuff, or if the distal rectal canal is severely stenotic (e.g., secondary to tumor, inflammatory condition, radiative injury, scarring).
- Do not use on patients with impacted stool.
- Do not use on patients having diarrhea.
- Do not use if package has been opened or damaged.

**WARNINGS**

- Feces contain infectious material. Protect from splatter which may occur when disconnecting or emptying the irrigation bags.
- Use only gravity or slow manual irrigation. Do not connect mechanical pumping devices to catheter irrigation lumen.
- Do not puncture the catheter body. Always use the catheter irrigation lumen. Do not puncture the catheter body with sharp objects.

**ADVERSE EVENTS**

- Feces contains infectious material. Protect from splatter which may occur when disconnecting or emptying the irrigation bags.

Care Tips for Certified Nursing Assistants and Patient Care Technicians

- Patients who may need a Bowel Catheter System
  - Patients who cannot control their bowel movements
  - Bedridden patients who cannot use a bedpan or commode
  - Patients whose skin may be harmed by stool
  - Patients with wounds in or near the sacral or perineal area
How to Take Care of Hollister Bowel Catheter Systems

- The catheter tubing should be positioned so that stool can drain/flow into the collection bag. To effectively drain the catheter tubing, position the catheter tubing straight and between the patient’s legs. Make sure the patient is not lying on the catheter tubing. The catheter tubing should not be twisted or kinked.
- Hang the collection bag at the end of the bed so the catheter tubing is not twisted and the collection bag is lower than the patient; this will help with drainage.
- Change the disposable odor-barrier collection bags when they are full to the 2000 mL line. Empty drainable bags when needed. Change drainable collection bags every seven days to help reduce odor. The bags connect and disconnect with a twist and lock movement. Follow hospital procedures for disposal.
- Make sure the catheter tubing is free of stool. Regularly strip the stool into the collection bag. Stool that collects and sits in the tubing may cause leakage and/or odor.
- Regularly cleanse any stool leakage from around the anus, and gently clean and protect the skin as usual.
- If stool is not flowing into the catheter, suggest that the RN irrigate the catheter.

Helpful Hints for the ActiFlo Indwelling Bowel Catheter System

- If the catheter is leaking or if the tubing is full of thick stool (not flowing), suggest that the RN irrigate the patient using the irrigation bag. Before irrigating, help position the patient on their side so the catheter may better drain the irrigant and stool.
- Make sure the anchor straps are secured correctly (refer to the instructions). If the patient has wounds or skin problems that prevent the use of the anchor straps, make sure the straps are taped down smoothly to the catheter tubing and are out of the way. Do not cut them off. If the straps are too tight, or cause redness, notify the RN.

Things to report to the nurse:

- The condition of the patient’s skin
- The color and thickness of the patient’s stool
- Amount of stool drained
- When the collection bags were last changed
- Any patient complaints or family concerns

This care tips guide is only intended to highlight select aspects of catheter insertion, maintenance, and removal. The RN is responsible for reviewing patient contraindications and precautions, consulting with a physician, and obtaining a physician’s order prior to the use of the product. A nurse can insert, remove, and irrigate the bowel catheter system.
How to Take Care of Hollister Bowel Catheter Systems

- The catheter tubing should be positioned so that stool can drain/flow into the collection bag. To effectively drain the catheter tubing, position the catheter tubing straight and between the patient’s legs. Make sure the patient is not lying on the catheter tubing. The catheter tubing should not be twisted or kinked.
- Hang the collection bag at the end of the bed so the catheter tubing is not twisted and the collection bag is lower than the patient; this will help with drainage.
- Change the disposable odor-barrier collection bags when they are full to the 2000 mL line. Empty drainable bags when needed. Change drainable collection bags every seven days to help reduce odor. The bags connect and disconnect with a twist and lock movement. Follow hospital procedures for disposal.
- Make sure the catheter tubing is free of stool. Regularly strip the stool into the collection bag. Stool that collects and sits in the tubing may cause leakage and/or odor.
- Regularly cleanse any stool leakage from around the anus, and gently clean and protect the skin as usual.
- If stool is not flowing into the catheter, suggest that the RN irrigate the catheter.

Helpful Hints for the ActiFlo Indwelling Bowel Catheter System

- If the catheter is leaking or if the tubing is full of thick stool (not flowing), suggest that the RN irrigate the patient using the irrigation bag. Before irrigating, help position the patient on their side so the catheter may better drain the irrigant and stool.
- Make sure the anchor straps are secured correctly (refer to the instructions). If the patient has wounds or skin problems that prevent the use of the anchor straps, make sure the straps are taped down smoothly to the catheter tubing and are out of the way. Do not cut them off. If the straps are too tight, or cause redness, notify the RN.

Things to report to the nurse:
- The condition of the patient’s skin
- The color and thickness of the patient’s stool
- Amount of stool drained
- When the collection bags were last changed
- Any patient complaints or family concerns

Dedicated to excellence.

For detailed clinical questions concerning our products: 1.888.740.8999
For orders only: 1.800.323.4060
www.hollister.com

Hollister and logo, Hollister ActiFlo and InstaFlo are trademarks of Hollister Incorporated. Covered under one or more of the following patents: US Patents 5,569,216, 7,147,627, 7,722,583, Australian Patents 1003207608, 2000274575, 2007201015, Canadian Patent 2421405, 2462570, Japanese Patent 4260107, and other patents pending.

This care tips guide is only intended to highlight select aspects of catheter insertion, maintenance, and removal. The RN is responsible for reviewing patient contraindications and precautions, consulting with a physician, and obtaining a physician’s order prior to the use of the product. A nurse can insert, remove, and irrigate the bowel catheter system.

*CAUTION: Prior to using a Hollister Bowel Catheter System (ActiFlo Indwelling Bowel Catheter System or InstaFlo Bowel Catheter System), be sure to read the entire Instructions for Use package insert supplied with the product for device Intended Use, Description, Contraindications, Warnings, Precautions, Adverse Events, and Instructions for Use.
ActiFlo Indwelling Bowel Catheter System

Product Information

NON STERILE: The ActiFlo Indwelling Bowel Catheter System is constructed primarily of silicone materials. All system components are sterile. Single patient use only.

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician or other healthcare practitioner licensed for that purpose.

CONTRAINDICATIONS

• Do not use if the patient’s distal rectum cannot accommodate the inflated volume of the retention cuff, or if the distal rectal canal is severely stenotic (e.g., secondary to tumor, inflammatory condition, radiation injury, scarring).

• Do not use on patients with impacted stool.

• Do not use a catheter with a record (less than 8 weeks old) rectal anastomosis, or a recent (less than 8 weeks old) anal or sphincter reconstruction.

• Do not use a catheter with compromised anal skin integrity (e.g., previous procidentia).

• Do not correct migration by use of an IUC.

• Do not attempt removal of an erosion by force.

WARNINGS

• Failure to comply with the following warnings may result in patient injury.

• Do not apply pressure to or damage the system.

• Do not use improper amount or type of fluids for irrigation or retention cuff inflation. NEVER use hot liquids.

• Do not use on infants and children younger than 2 years old.

• Inflation of the distal rectum balloon causes complete occlusion. Do not use drop-fall balloon inflated in an unattended patient. To verify complete deflation of the drop-fall balloon, expel air and use RED CONNECTOR (CT800-21 or -71).

• Do not use on patients with severe tenesmus, or patients who experience tenesmus or severe pain after insertion of the catheter.

• Caution should be observed in patients whose rectum may be altered by stricture due to radiation or affected by an underlying disease conditions. Immediately consult a physician if rectal bleeding is suspected.

• Do not use the InstaFlo Bowel Catheter on patients who may bleed easily due to anticoagulant / antiplatelet therapy or undergoing disease conditions. Immediately consult a physician if rectal bleeding is suspected.

• After use, this system is a biohazard. Handle and dispose of in accordance with institutional protocol and universal precautions for contaminated waste.

WHERE TO Purchase

• Patients who may need a bowel catheter system

InstaFlo Bowel Catheter System

Product Information

NON STERILE: The InstaFlo Bowel Catheter System is constructed primarily of silicone materials. All system components are sterile. Single patient use only.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or other healthcare practitioner licensed for that purpose.

CONTRAINDICATIONS

• Do not use if the patient’s distal rectum cannot accommodate the inflated volume of the retention cuff, or if the distal rectum canal is severely stenotic (e.g., secondary to tumor, inflammatory condition, radiation injury, scarring).

• Do not use on patients with impacted stool.

• Do not use a catheter with a record (less than 8 weeks old) rectal anastomosis, or a recent (less than 8 weeks old) anal or sphincter reconstruction.

• Do not use a catheter with compromised anal skin integrity (e.g., previous procidentia).

• Do not correct migration by use of an IUC.

• Do not attempt removal of an erosion by force.

WARNINGS

• Failure to comply with the following warnings may result in patient injury.

• Do not apply pressure to or damage the system.

• Do not use improper amount or type of fluids for irrigation or retention cuff inflation. NEVER use hot liquids.

• Do not overinflate retention cuff.

• Do not use on patients having recent (less than 6 weeks old) rectal anastomosis, or a recent (less than 6 weeks old) anal or sphincter reconstruction.

• Do not use on patients with compromised anal skin integrity (e.g., previous procidentia, mucosal ulceration).

• Patients may need a bowel catheter system

Care Tips for Certified Nursing Assistants and Patient Care Technicians

Patients Who May Need a Bowel Catheter System

• Patients who cannot control their bowel movements

• Bedridden patients who cannot use a bedpan or commode

• Patients whose skin may be harmed by stool

• Patients with wounds in or near the sacral or perianal area

ActiFlo Indwelling Bowel Catheter System

©2011 Hollister Incorporated. Printed in USA 011320-271

A Hollister Technology

ActiFlo Indwelling Bowel Catheter System

Hollister Incorporated

Liberityville, IL, USA
1.888.740.8999

Distributed by Hollister Limited

Arizona, Canada
1.800.263.7400